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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,161	12/15/2003	Kevin T. Foley	64118.000045	2165

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EXAMINER	
WILLSE, DAVID H	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,161	FOLEY ET AL.	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-3-06; 8-10-06; 8-21-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Applicant's remarks and the Declaration by Dr. Kevin T. Foley, both submitted on July 3, 2006, have been considered. The Applicant refers to several passages in US 5,792,044 as to surgical procedures in which all steps using multiple tools are conducted through a single working cannula, the size of which can be selected according to the procedure to be performed. The Applicant also discusses vertebral fixation elements (US 5,792,044: column 15, line 3 et seq.), a bone screw being threaded into a pedicle of a vertebra (*ibid.*: column 15, lines 29-34), and repositioning of the cannula (*ibid.*: column 12, lines 11-12). The Applicant concludes that "it would have been readily apparent to one skilled in the art that the specification discloses inserting pedicle screws through a single cannula and securing them to vertebrae, inserting another fixation element such as a plate or rod through the single cannula, and securing the plate or rod to the pedicle screws" (Applicant's reply of July 3, 2006: page 12, lines 14-17). Back on March 22, 1996, the purported date of the currently claimed invention, the ordinary practitioner (not to mention patients) would have been quite enthused to learn that such unwieldy implants as spinal stabilization plates and rods could be secured along a patient's spine via a single, relatively small incision, yet the Applicant's '044 patent says not a word about such plates or rods or even pedicle screws. The '044 patent does mention the insertion of a bone screw into a pedicle of a vertebra but fails to state the purpose of such a screw, which could potentially be used for treating a fracture (column 14, lines 22-26) or for anchoring a prosthesis. The missing descriptive matter (i.e., "pedicle screw") is therefore not inherent in said patent (MPEP § 2163, section II). The Applicant relies upon column 15, lines 3-4, and column 4, lines 12-15, of the '044 patent in an attempt to show support for *more than one* fixation element fixing together a single pair of vertebrae (as set forth in new claim 9), but the sentence at column 15, lines 3-4, of

said patent is a generalized statement to show the versatility and/or reusability of the device **10**, as are the two statements immediately preceding that sentence. In the actual description of the procedure (US 5,792,044: column 15, lines 4-20), "fixation element" appears in singular form only.

With regard to the method in general, carving out an undisclosed species from a generally described method is prohibited under 35 U.S.C. 112, first paragraph (MPEP § 2163.05, sections II and III), and the examiner, after again thoroughly reviewing US 5,792,044 in its entirety, finds that the methods of instant claims 1-8 cannot even be considered a "species" of the methods disclosed in US 5,792,044. Contrary to what is suggested in paragraph 19 of Dr. Foley's Declaration, nowhere does the '044 patent describe repositioning a single cannula at a single incision to access various sites *on different vertebrae* for installing spaced apart implants. Instead, the cannula is repositioned to appropriately center the working space over the target region of the spine (US 5,792,044: column 12, lines 7-11), "to allow a greater region of bone removal" (*ibid.*: column 13, lines 54-56), to properly locate a bone screw (*ibid.*: column 15, lines 15-20), and/or to insert graft material into a disc space location (*ibid.*: column 16, lines 1-9). The discussion of mult-level laminectomies and foramenotomies would have afforded the Applicant the perfect opportunity to inform the public of the supposed discovery that all of the surgical steps on spaced apart working spaces at different discs or vertebrae can be performed through a single working cannula at a single incision site, yet the Applicant instead either *sequentially* inserts the cannula **20** through *several* small incisions along the spinal mid-line or uses *several* cannulas **20** placed at *each* of the small incisions (*ibid.*: column 13, line 62, through column 14, line 2). How does the Applicant expect the ordinary practitioner to have inferred the claimed

method from a patent which tends to teach away from such a procedure, particularly in view of the fact that the undisclosed spinal rod or plate installation method as claimed would have been even more complex?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Davison et al., WO 02/09801 A1: Figures 5 and 29-38; page 18, line 9, through page 19, line 1; page 54, lines 5-18; page 60, lines 1-20; page 61, line 18, through page 62, line 10; etc.

Claim 9 is rejected under 35 U.S.C. 102(e) and 35 U.S.C. 102(b) as being clearly anticipated by Kuslich et al., US 5,489,307: abstract; figures; column 14, lines 20-24. (It is also noted that the Kuslich et al. device, like most spinal fusion implants, does *not* involve spinal stabilization rods or plates.)

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dave Willse
Primary Examiner
Art Unit 3738